APPENDIX F 510(k) SUMMARY

K043274

JAN 28 2005

Applicant:	Neuromonics Pty Ltd (formerly TinniTech Ltd) Unit 10-11/ 56 Neridah St Chatswood NSW 2067 Australia Phone: +61 2 9410 4300 Fax: +61 2 9410 4302
Date of Submission:	November 2004
Manufacturing Site:	Neuromonics Pty Ltd Unit 10-11/ 56 Neridah St Chatswood NSW 2067 Australia
Establishment Registration Number:	8020057
Distributor:	Mr R West, Go West, Inc. 2502 Tournament Court Castle Rock CO 80104 Phone/Fax: (303) 663-8089
Contact Name for Submission:	Ben McSweeney (contact address as per Applicant)
Trade or Proprietary Name	NEUROMONICS TINNITUS TREATMENT
Common or Usual Names	Tinnitus Masker
Classification Name (FDA)	KLW: Masker Tinnitus
Classification	Class II device
Reason for Submission	New Device

15

Indications for Use

The Neuromonics Tinnitus Treatment System has been designed solely and specifically for delivering and monitoring the audio stimulus required for the Neuromonics Tinnitus Treatment.
The Neuromonics Tinnitus Treatment is intended to provide relief from the disturbance of tinnitus, while using the system, and with regular use (over several months) may provide relief to the patient whilst not using the system.

The Neuromonics Tinnitus Treatment System comprises a SD Memory Card that is pre-recorded with selected relaxation audio and other sounds spectrally adapted to suit the particular patient's hearing thresholds. The system is indicated to provide a high degree of interaction (or masking) and intermittent interaction / masking with the patients' tinnitus perception, as part of the Neuromonics tinnitus management program. The addition of the music is to aid the promotion of relaxation during the tinnitus masking process.

Intended Use

The Neuromonics Tinnitus Treatment System is intended to interact and intermittently interact with the patients tinnitus as part of a tinnitus management program. The addition of the music is to aid the promotion of relaxation during the tinnitus interaction process.
The initial hearing and tinnitus tests are conducted by a qualified audiologist familiar with the treatment of tinnitus; the subsequent management of the treatment is carried out by an appropriate healthcare professional.

Target Population

The target population for the device is adults (18 years and over) who present with tinnitus that may or may not be accompanied with hearing loss at the higher frequencies and who are participating in a tinnitus management program.

Substantial Equivalence

Neuromonics is claiming substantial equivalence to three devices:

Equivalence is claimed to the TinniTech ANMP System, manufactured by Neuromonics (formerly TinniTech), 510k number SD K030791

Equivalence is claimed to the Dynamic Tinnitus Mitigation System, DTM-6 manufactured by Petroff Audio Technologies Inc. 510k number; K974501
Equivalence is also claimed to the Custom TCI Instrument manufactured by Siemens Hearing Instruments, 510k number; K011364.

K030791

The continuous and intermittent interaction stimulus that a tinnitus patient receives from the TinniTech ANMP System K030791, remains exactly the same for the Neuromonics Tinnitus Treatment System.
The TinniTech ANMP System device was upgraded to the Neuromonics Tinnitus Treatment System to address specific Neuromonics Tinnitus Treatment patient's useability requirements.

K974501

The Neuromonics Tinnitus Treatment Phase 1 audio signals, like CDs #2, #3 and #4 of the predicate device, provide digital tinnitus interaction sounds together with selected musical sounds to promote relaxation during the tinnitus interaction process.

K011364

Like the predicate device, K011364, the Neuromonics Tinnitus Treatment custom-tailors the audio signals on both Phase 1 and Phase 2 audio to suit the individual patients' hearing requirements. This is achieved through analysing the patient's audiogram and boosting the amplitude of those frequencies where the patient has been shown to have a reduced hearing threshold.

The Neuromonics Tinnitus Treatment also includes on the Phase 2 audio signal, specially selected music with a dynamic characteristic that allows the patient's tinnitus sound to intermittently break through the interaction effect of the music. This function, like the predicate device K011364, assists in enhancing the patient's habituation to the tinnitus sound.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2005

Neuromonics Pty, Ltd.
c/o Mr. Ben McSweeny
Unit 10-11/56 Neridah St
Chatswood NSW 2067

Re: K043274
Trade/Device Name: Neuromonics Tinnitus Treatment
Regulation Number: 21 CFR §874.3400
Regulation Name: Tinnitus Masker
Regulatory Class: Class II
Product Code: KLW
Dated: November 26, 2004
Received: November 26, 2004

Dear Mr. McSweeny:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K043274

Device Name: **Neuromonics Tinnitus Treatment System**

Indications for Use:

The Neuromonics Tinnitus Treatment System comprises an SD Memory Card, the Neuromonics Processor, a portable, stereo, MP3 player, and Earphones. The Memory Card has been pre-recorded with selected relaxation music and other sounds spectrally adjusted to suit the particular patient's spectral hearing thresholds as shown by their audiogram. The sounds on the SD Memory Card are reproduced by the Neuromonics Processor and delivered to the ears by the Bang and Olufsen earphones. The device is indicated for adult (18 years and over) tinnitus sufferers who may or may not suffer hearing loss and are participating in the Neuromonics Tinnitus Treatment.

The Neuromonics Tinnitus Treatment System is for home use under the direction of an appropriately qualified healthcare professional such as an otolaryngologist, an audiologist, or a licensed hearing aid dealer.

Patients should receive a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) to rule out medically or surgically treatable diseases for which tinnitus is a symptom before proceeding with the Neuromonics Tinnitus Treatment.

The Neuromonics Tinnitus Treatment System may be used to fully and intermittently interact with / mask their tinnitus perception.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Janine K. Kane Ph.D.
(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K043274